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 APPLICATION NO.
 FILING DATE
 FIRST NAMED INVENTOR
 ATTORNEY DOCKET NO.

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MICHAEL L GOLDMAN NIXON PEABODY LLP CLINTON SQUARE PO BOX 1051 ROCHESTER NY 14603 ZARA, J

ART UNIT PAPER NUMBER

1635

DATE MAILED: 08/10/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks



Applicant(s)

Office Action Summary

09/428,371

Soderlund et al.

| | * | |
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| xaminer | Group Art Unit | |
| Zara, Jane | 1635 | |
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| Responsive to communication(s) filed on | | |
|--|---|--|
| ▼ This action is FINAL. | | |
| Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quay/1035 C.D. 11; 453 O.G. 213. | | |
| A shortened statutory period for response to this action is set to expirelonger, from the mailing date of this communication. Failure to respond wit application to become abandoned. (35 U.S.C. § 133). Extensions of time r 37 CFR 1.136(a). | thin the period for response will cause the | |
| Disposition of Claim | | |
| | is/are pending in the applicat | |
| Of the above, claim(s) | is/are withdrawn from consideration | |
| Claim(s) | | |
| ☑ Claim(s) <u>41-52 and 78-83</u> | is/are rejected. | |
| ☐ Claim(s) | | |
| ☐ Claims | | |
| Application Papers | | |
| ☐ See the attached Notice of Draftsperson's Patent Drawing Review, P | TO-948. | |
| ☐ The drawing(s) filed on is/are objected to by the Examiner. | | |
| ☐ The proposed drawing correction, filed on is ☐ approved ☐disapproved. | | |
| ★ The specification is objected to by the Examiner. ★ The specification is objected to by the Examiner. ★ The specification is objected to by the Examiner. ★ The specification is objected to by the Examiner. ★ The specification is objected to by the Examiner. ★ The specification is objected to by the Examiner. ★ The specification is objected to by the Examiner. ★ The specification is objected to by the Examiner. ★ The specification is objected to by the Examiner. ★ The specification is objected to by the Examiner. ★ The specification is objected to by the Examiner. ★ The specification is objected to by the Examiner. ★ The specification is objected to by the Examiner. ★ The specification is objected to be a specification is ob | | |
| ☐ The oath or declaration is objected to by the Examiner. | | |
| Priority under 35 U.S.C. § 119 | | |
| ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d). | | |
| ☐ All ☐Some* None of the CERTIFIED copies of the priority documents have been | | |
| received. | | |
| received in Application No. (Series Code/Serial Number) | | |
| received in this national stage application from the International Bureau (PCT Rule 17.2(a)). | | |
| *Certified copies not received: | | |
| Acknowledgement is made of a claim for domestic priority under 35 t | J.S.C. § 119(e). | |
| Attachment(s) | | |
| X Notice of References Cited, PTO-892 | | |
| ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s) | | |
| ☐ Interview Summary, PTO-413 ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948 | | |
| ☐ Notice of Informal Patent Application, PTO-152 | | |
| | | |
| SEE OFFICE ACTION ON THE FOLLOWING PAGES | | |

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This action is in response to the amendments filed on June 7, 2000.

DETAILED ACTION

Claims 41-52 and 78-83 are pending in the instant application.

Priority

The updated status of Application Serial No. 08/772,512, now US Patent No. 6,022,705, has to be included in the first line of the specification.

Response to Arguments and Amendments

<u>Retained Rejections</u>

Claims 41-52 and 78-83 stand rejected under 35 U.S.C. 112 for the same reasons of record as set forth in the Office Action mailed March 13, 2000, Paper No. 8.

Applicant's arguments filed June 7, 2000, Paper No. 9, have been fully considered but they are not persuasive. Although applicants have provided references in the specification for general protocols for the introduction of nucleic acid molecules into host cells, no evidence has been provided in the instant application, nor in the priority documents listed, for the successful and functional expression of the deduced proteins encoded by the nucleotide sequences of SEQ ID Nos: 1 and 2, which deduced amino acid sequences comprise SEQ ID Nos: 3 and 4 respectively. The claimed invention is drawn to methods of screening chemical agents for their ability to modify voltage sensitive sodium channel function comprising assaying changes in the

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function of expressed voltage sensitive sodium channels in an appropriate host cell upon exposure of the expressed sodium channels to candidate chemical agents (i.e. insecticides). Such methods are contingent upon the successful expression of such voltage sensitive sodium channels in appropriate host cells, such that, upon exposure to a chemical agent, the transport of sodium or guanidinium is altered. At the time the invention of the instant application was made, the deduced amino acid sequences comprising an insecticide susceptible voltage sensitive sodium channel (SEQ ID Nos: 1 and 3) and an insecticide resistant voltage sensitive sodium channel (SEQ ID Nos: 2 and 4) had been disclosed by Knipple et al (Knipple et al. 1994, Proc. Natl. Acad. Sci., Vol. 91, Pages 2483-2487) and Williamson et al (Williamson et al. 1996, Mol. Gen. Genet., Vol. 252, pages 61-60), but no expression data was provided. Therefore, no convincing evidence has been provided that applicants had possession of the claimed invention: functional expression of SEQ ID Nos: 3 or 4, which would distinguish the data disclosed in the instant application from that already disclosed by others at the time the invention was made.

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Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after Application/Control Number: 09/428,371

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jane Zara whose telephone number is (703) 306-5820. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. George Elliott, can be reached on (703) 308-4003. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

JZ

August 3, 2000